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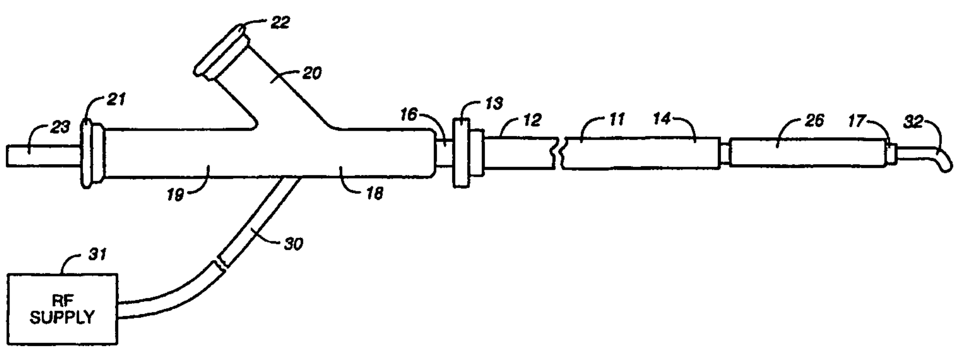

(57) Abstract

The present invention provides a device and method for closing a patent foramen ovale. The present invention comprises a catheter sheath (11) with proximal, and distal ends. A catheter (16) is deployably retained within the catheter sheath. An electrode (26) is provided at the distal end of the catheter such that the adjacent tissue can be heated using radio frequency (RF) energy. Once the catheter sheath is placed by a trained health care professional across a patent foramen ovale, the catheter is advanced such that the electrode is deployed outside of the distal end of the catheter sheath. The catheter sheath is then removed from the foramen ovale, and (RF) energy is applied to the electrode to heat adjacent tissue that causes thermal trauma to the lining of the foramen ovale. The catheter is then repositioned into the distal end of the catheter sheath, and then removed from the patient. The traumatized area created along the inner surfaces of the patent foramen ovale heals over time, and turns into a scar obliterating the foramen ovale.

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A CATHETER FOR CAUSING THERMAL TRAUMA TO A PATENT FORAMEN OVALE AND METHOD OF USING THE CATHETER

FIELD OF THE INVENTION

The present invention is related generally to medical/surgical devices that can be placed within the body of a patient to perform a procedure. More specifically, the present invention is a minimally invasive device useful in closing a patent foramen ovale.

BACKGROUND OF THE INVENTION

The fetal circulation is vastly different than the normal adult circulation. The blood circulating in a fetus is oxygenated by the placenta, not the developing lungs. Therefore, the fetal circulation directs only a small percentage of the circulating blood to the fetal lungs. Most of the circulating blood is shunted away form from the lungs to the peripheral tissues through specialized vessels and foramens that are open ("patent") during fetal life. In most people these specialized structures quickly close after birth, unfortunately, sometimes they fail to close and create hemodynamic problems that can be fatal if left untreated.

The fetal circulation is illustrated in Fig. 1. The umbilical arteries branch off of the iliac arteries and deliver unoxygenated (blue) blood to the placenta. The fetal blood travels through the capillary bed in the placenta and transfers carbon dioxide to the maternal blood and takes oxygen and other nutrients from the maternal blood. The umbilical vein returns oxygenated (red) blood to the fetus. Most of the oxygenated blood from the umbilical vein bypasses the developing liver and travels through a specialized vessel called the ductus venosus to the inferior vena cava and then into the right atrium. A good portion of the oxygenated blood from the inferior vena cava is directed across the right atrium and into the left atrium through a specialized curtain like opening in the heart called the foramen ovale. The blood

from the left atrium then enters the left ventricle and then into the aorta where it travels to the head and other body tissues delivering the needed oxygen and nutrients.

The small amount of blood entering the right atrium that does not pass through the foramen ovale, most of which comes from the superior vena cava, flows into the right ventricle and then gets pumped into the pulmonary trunk and pulmonary arteries. Some of this blood is pumped into the developing lungs. However, the fetal lungs are collapsed which causes a high resistance to blood flow. Another specialized vessel, called the ductus arteriosus, is a vessel that connects the high pressure pulmonary artery to the lower pressure aorta. Therefore, most of the blood in the pulmonary artery flows into the lower pressure aorta through this specialized vessel.

Upon birth, the circulatory system goes through profound changes. The flow through the umbilical arteries and umbilical vein stops and consequently the flow through the musculature around the ductus venosus constricts and the blood flow through the ductus venosus stops. The lungs fill with air and the resistance to blood flow into the lungs drastically decreases. The corresponding pressure in the right atrium, right ventricle, and pulmonary arteries also decrease. The decrease in pressure in the right atrium causes the curtain like opening of the foramen ovale to close, driving more blood into the right ventricle and then to the lungs for oxygenation. Over time, the foramen ovale is replaced with a membrane called the fossa ovalis. Similarly, the decrease in pressure in the pulmonary arteries reduced the pulmonary arterial pressure to the same as or slightly less than the pressure in the aorta, which stops or reverses the flow through the ductus arteriosus. Once the muscular tissue of the ductus arteriosus is perfused with well oxygenated blood, the muscle begins to constrict and close the ductus arteriosus. The ductus arteriosus normally closes within about one week of life.

Usually over time, the unique openings of the fetal circulation become obliterated and a solid mass of tissue forms where these opening once were. However, in some people the openings remain. A patent ductus venosus after birth is very rare and almost always fatal. A patent ductus arteriosus occurs in about 1 out

of every 5000 births. The patent ductus arteriosus once diagnosed is either medically treated or surgically ligated to close the ductus. In about one of four people, the foramen ovale does not seal shut, instead it remains patent. Since the pressure in the left atrium is about two to four mm Hg greater than the pressure in the right atrium, the curtain like opening usually remains shut. However, if the pressure in the right atrium increases, such as upon heavy lifting or while performing a Val Salva type maneuver, the curtain like fold of tissue opens and the blood flows from the right atrium to the left ventricle.

Studies have shown that adults with strokes of unknown origin (cryptogenic strokes) have about twice the normal rate of patent foramen ovales than the normal population. Although there is a correlation between strokes and patent foramen ovales, it is currently unknown why this correlation exists. Many people theorize that blood clots and plaque that have formed in the peripheral venous circulation (in the legs for example) break off and travel to the heart. Normally, the clots and plaque get delivered to the lungs where it is trapped and usually cause no harm to the patient. Patients with a patent foramen ovale, however, have a potential opening that the clots or plaque can pass through the venous circulation and into the arterial circulation and then into the brain or other tissues to cause a thromboembolic event like a stroke. The clots may pass to the arterial side when there is an increase in the pressure in the right atrium. Then the clots travel through the left side of the heart, to the aorta, and then to the brain via the carotid arteries where they cause a stroke and the associated neurological deficits.

Currently, the method of choice to close a patent foramen ovale is open heart surgery and ligation of the foramen ovale to close it. This obviously is associated with the usually risks of general anesthesia, open heart procedures, infections, etc. Another method is a catheter based method which places to opposing umbrella shaped devices around the foramen ovale, one in the right atrium and one in the left atrium. Unfortunately, this procedure is technically difficult and leaves behind two foreign objects that could dislodge or cause a thromboembolus which could break off and cause thromboembolic events. What is needed therefore is a least invasive method for closing a patent foramen ovale which does not have the associated risk of

an open heart procedure, is technically easy to perform, and which does not leave any foreign material behind.

SUMMARY OF THE INVENTION

The present invention provides a device and method for closing a patent foramen ovale. The present invention comprises a catheter sheath with proximal and distal ends. A catheter is deployably retained within the catheter sheath. An electrode is provide at the distal end of the catheter such that adjacent tissue can be heated using radio frequency ("RF") energy. Once the catheter sheath is placed by a treating health care professional across a patent foramen ovale, the catheter is advanced such that the electrode is deployed outside of the distal end of the catheter sheath. The catheter sheath is then removed from the foramen ovale and RF energy is applied to the electrode to heat adjacent tissue that causes thermal trauma to the lining of the foramen ovale. The catheter is then repositioned into the distal end of the catheter sheath and then removed from the patient. The traumatized area created along the inner surfaces of the patent foramen ovale heals over time and turns into a scar obliterating the foramen ovale.

BRIEF DESCRIPTION OF THE DRAWINGS

As used herein, like reference numerals will designate similar elements in the various embodiments of the present invention wherein:

Fig. 1 is a schematic diagram of the fetal circulation of a mammal;

Fig. 2 is a schematic diagram of a catheter of the present invention traveling up the inferior vena cava of a patient into the right atrium and through the foramen ovale;

Fig. 3 is a schematic plan view of a foramen ovale catheter of the present invention;

Fig. 4 is an axial cross-sectional view of the distal end of the catheter of Fig. 3;

Fig. 5 is a perpendicular cross-sectional view of the catheter of Fig. 3 taken along the plane indicated in Fig. 4 by line 5-5;

Fig. 6 is an axial cross-sectional view of the proximal end of the present invention;

Fig. 7 is a side view of an alternate embodiment of the present invention;

Fig. 8 is a bottom view of the embodiment of Fig. 7;

Fig. 9 is a bottom view of an alternate embodiment similar to the embodiment of Fig. 8 utilizing bicolor energy; and

Fig. 10 is a plan view of an alternate embodiment similar to the embodiment of Fig. 3 utilizing bicolor energy.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides a novel least invasive device and method for closing a patent foramen ovale in a mammal. The device is specifically designed to be used in catheterization laboratories in hospitals for treating humans as well as veterinary hospitals for treating animals. As used herein the term "patient" shall refer to human patients as well as animal patients. As illustrated in Fig. 2, the device is introduced into the blood stream using well known catheterization procedures. The device is initially introduced within a catheter sheath 11 with a distal end 14. The device then extends distally from the catheter sheath to span the patent foramen ovale. The device has an RF electrode 26 at the distal end. RF energy is applied to the adjacent tissue using the electrode to thermally traumatize the interior tissue of the foramen ovale. After heat has been applied for sufficient amount of time the device is removed from the patient. Once the interior of the foramen ovale has been traumatized, the body's healing mechanism begins. Because the pressure within the left atrium is greater than the pressure in the right atrium, the curtains of tissue that comprises the patent foramen ovale are directly opposed to each other. The body's healing mechanism then replaces the traumatized tissue with scar tissue and the scar tissue forms across the curtain of tissue permanently sealing the foramen ovale. Over time, the foramen ovale becomes completely obliterated and turns into the

normal fossa ovalis.

Turning now to Fig. 3, the foramen ovale catheter of the present invention is further illustrated. In order to obtain access to the blood stream, the foramen ovale catheter has to be advanced through the skin of the patient into a blood vessel, preferably a standard femoral vein catheterization is used that is well known in the art, however other vessel access to the atriums can be used. Typically, a standard introducer is used to gain access from the skin of the patient to the lumen of the vessel. These introducers are commercially available from many different manufacturers, Cordis Corporation of Miami Florida being one, Cook of Bloomington Indiana being another. The introducer can be of many different sizes, in the preferred embodiment the introducer varies from a 6 French to a 15 French introducer. Presently it is preferred to use a 7 or 8 French introducer. The introducers usually have a hollow shaft 12, a tapered distal end 13, a catheter access port 16 with an internal seal (not illustrated) to ensure that fluids do not leak from the access port, and an irrigation port 15 connected via flexible tubing 14. The irrigation port is used to flush the introducer and to inject anticoagulant or other medications directly into the vessel.

A sheath catheter 11 is then advanced through the catheter port of the introducer. The catheter has a proximal end 12 and a distal end 14. Provided at the proximal end is a port access 13 which allows the electrode catheter to be introduced through the sheath catheter. The outer diameter of the sheath catheter can vary from about 5 French to about 15 French. The inner diameter is such that a 4 French to about a 14 French foramen ovale catheter can be placed within its lumen. In the preferred embodiment, the sheath catheter is a single lumen catheter made by extruding standard catheter materials using standard extrusion techniques. Currently it is preferred to extrude polyether-block-amide, nylon, polyurethane, polyimide, or a polyolefin copolyester. However, any other extrudable catheter material well known in the art can be used to manufacture the catheter. The smaller the catheter, the stronger the extruding material should be. With very small catheters, the catheter can be reenforced by using braided meshing, a technique already well known in the catheter arts. The sheath catheter's length is such that it can easily be used from a

femoral site to reach an atrium of the heart, about 80 to 140 cm, with about 120 . cm being preferred. Optionally, the distal end of the sheath catheter can have a radio-opaque marker 24 such as a metallic ring placed around the distal end or incorporated into the distal end such that the distal end is visible under imaging techniques such as fluoroscopy.

Inserted inside the sheath catheter's lumen is a foramen ovale electrode catheter 16 of the present invention. The foramen ovale electrode catheter can be made by extruding standard catheter materials using standard extrusion techniques, just like the sheath catheter. The catheter has a proximal end 18 provided with a standard "Y" fitting 19 and a distal end 17. The Y fitting comprises a standard port 21 for the placement of a guide wire 23. The guide wire can be any standard guide wire in the industry. Typically, the guide wire is made out of a coil and has a blunt distal end 32 to prevent damage to vessels when the catheter is advanced. The angled stem 20 of the Y fitting is provided with a lure lock type fitting 22 which is used to control fluids that are injected into the patient such as anticoagulants and contrast media. Typically a syringe is connected to the port to inject the fluids. A standard cable 30 with optional connectors is also provided at the proximal end of the electrode catheter. The cables are connected to a supply 31 of RF energy.

Located at the distal end of the foramen ovale electrode catheter is the electrode 26. Referring now to Figs. 3-5, the foramen ovale catheter can be comprised of two catheters, the outer catheter 16 which is placed within the catheter sheath, and an inner catheter 25 which has a lumen 40 for the guide wire 23. Between the outer and inner catheter is an area 36 for fluid to communicate with the fluid port and the distal end 17 of the outer catheter and the distal end 24 of the inner catheter.

The inner and outer catheters are manufactured using well known materials and well known extrusion techniques. The outer catheter typically has an outer diameter of about 6 French to about 14 French, with 8 French being presently preferred. Between the outer and inner catheter is an area 36 for fluid to pass through the catheter. The inner catheter is sized to fit within the outer catheter leaving adequate room for the fluid space 36.

An RF electrode 26 is bonded to the outer circumference of the outer catheter near its distal end. The electrode can be made out of any standard biocompatible electrode material well known in the art. Presently platinum or platinum alloys are preferred, however steel electrodes could also be used. A lead wire 46 that spans the length of the catheter from the Y fitting to the electrode is threaded between the outer and inner catheters in the space 36. A hole 33 is created in the outer catheter and the lead wire is threaded through the hole and welded to the electrode. During the manufacturing process, the lead wire is threaded through the outer catheter first and then welded to the electrode. The electrode is then placed over the distal end of the outer catheter and the slack on the lead wire is taken up by pulling on its proximal end. The electrode is then bonded to the outer catheter by wicking in an appropriate adhesive.

Optionally located on the inner surface of the electrode on the opposite side from the lead wire is a standard means 48 for monitoring the temperature of the electrode. Presently a standard thermocouple made out of copper and constantan wire is used. The temperature monitoring means are connected with appropriate lead wires to the Y fitting. The monitoring means is placed on the inner surface of the electrode by making a hole 34 in the outer catheter. The monitoring means is then bonded to the inner surface of the electrode prior to the electrode being placed over the distal end of the outer catheter. The catheter could optionally be provided with a plurality of thermocouple leads.

The RF energy used is typical RF energy ranging from about 100 kHz to about 1000 kHz, with about 460 kHz being presently preferred. The watts of power can vary from about 0.1 watt to about 100 watts, with a range of about 3 watts to 25 watts being presently preferred. Many different RF generators can be used to supply the RF energy. Presently, an RF generator manufactured by Stellartech Research Corporation of Mountain View, CA is preferred. The RF generator can deliver a maximum wattage of RF energy, with that maximum wattage chosen by the user of the generator. The RF generator then can measure the temperature at a thermocouple inside the needle to then regulate the wattage to maintain a set temperature. Presently, temperatures ranging from about 45 degrees centigrade to

about 99 degrees centigrade is used with a temperature of 85 degrees centigrade being presently preferred. The RF energy can be delivered for a set time ranging from 1 second to 500 seconds with 30 seconds being presently preferred.

Connected to the RF supply is a standard reference electrode (not illustrated) that is also connected to the skin of the patient. The RF energy being supplied to the electrode 26 of the electrode catheter is unipolar current. The reference electrode is used to complete the circuit from the electrode catheter to the RF supply.

Turning now to Fig. 6, a preferred Y type fitting 19 is illustrated. The proximal end of the outer catheter 16 is bonded in the distal end 53 of the Y fitting with bonding material 52. The proximal end of the inner catheter extends proximally past the fluid port 20 and is bonded in the middle of the Y fitting with bonding material 51. Thus, as can be appreciated by the drawing, the lumen 58 of the fluid port is in direct communication with the fluid space 36 between the inner and outer catheters. The guide wire port 57 at the most proximal end of the Y fitting is slightly tapered. The taper then increases to a conical section 54 until the inner diameter 55 is about identical to the inner diameter of the inner catheter. The tapering makes it easy to place the guide wire through the lumen 40 of the inner catheter. The cable 30 is connected to the Y fitting opposite the Y arm 20. The lead wires and thermocouple wires traverse through the Y fitting and into the space between the inner and outer catheters.

Figs. 7 and 8 illustrate a further embodiment of the present invention. A sheath catheter 61 with a distal end 63 is illustrated in cross-section. Within the lumen of the sheath catheter is a foramen ovale catheter 67. In this embodiment the foramen ovale catheter is a single lumen catheter that has a paddle electrode 68 attached at its distal end. The paddle electrode has a relatively flat profile with a thickness of about 0.050 inches. The width of the paddle is sized such that if fits within the sheath catheter and is wider than the diameter of the foramen ovale catheter. The paddle electrode has a stem 69 for insertion and bonding to the interior of the foramen ovale catheter. A lead wire (not illustrated) spans the length of the foramen ovale catheter within the lumen of the catheter from the proximal end to the electrode. Optionally, a means from monitoring temperature 72 is bonded to the

bottom surface of the electrode. Presently a thermocouple is used with copper and constantan wires 71.

Fig. 9 is an alternate embodiment of the present invention similar to the embodiment of Fig. 7 however utilizing bipolar energy to thermally traumatize the tissue touching the electrodes. In this embodiment, the paddle 80 is actually an insulator such as nylon or a polyester. Attached the paddle are two different electrodes 81 and 82, one for the positive electrode and one for the negative electrode. The electrodes can be metal electrode bonded to the paddle. Currently it is preferred that the electrodes are manufactured by ion implanting or sputtering silver, gold, or platinum on the surface of the paddle covering the two different edges where the electrodes are located. Separate lead wires 83 and 84 are attached to each electrode. Bipolar energy can then be applied to the tissue in contact with the electrodes to heat the tissue. The bipolar energy will tend to stay on the surface of the tissue instead of penetrating the tissue like unipolar energy. Obviously, with using the bipolar electrodes there is no need for using a reference electrode attached to the skin of the patient.

Fig. 10 is an alternate embodiment of the present invention similar to the embodiment of Fig. 3 utilizing bipolar energy. In this embodiment the electrode comprises insulators 96 separating alternating positive electrodes 97 and negative electrodes 98. The insulator would not conduct RF energy. The electrodes could be ion implanted, sputtered, bonded, or otherwise attached to the insulating material that creates the insulators 96. Preferably the electrode is manufactured by using a polyester cylinder and ion implanting silver, gold, or platinum. Each positive and negative electrodes would have separate lead wires connecting them to the supply of RF energy.

Those acquainted with medical procedures will appreciate that any medical procedure involving the heart should be practiced only by health care professionals with extensive training and experience in cardiology and/or cardiac surgery. Therefore the present invention provides for a method of training a person to perform the procedure of traumatizing a patent foramen ovale using the disclosed embodiments. The method of training includes the steps of demonstrating the

device, supervising the person being trained, and the labeling instructions included with the device on when and how to use the device.

The embodiments of the present invention are all used similarly. First, access is gained to a blood vessel. Typically the femoral vein is catheterized using any one of may commercially available introducing catheters that are well known in the art. Once the introducing catheter is in place, a single lumen sheath catheter that is long enough to reach the foramen ovale and is large enough to allow the particular embodiment of the present invention to pass through the lumen is placed through the introducing catheter. An example of this type of catheter is the 8 French Mullins Introducer Set manufactured by Cook of Bloomington IN. Typically these catheters are provided with a fairly stiff guide wire to allow for probing the right atrium for the foramen ovale. The single lumen catheter is advanced to the right atrium and then through the foramen ovale to the left atrium.

Next the guide wire is removed and the foramen ovale catheter is advanced in the single lumen catheter to the left atrium. The single lumen catheter is then removed from the left atrium and the foramen ovale.

The electrode is then placed within the foramen ovale and RF energy is applied to heat the adjacent tissue. The energy is applied for a sufficient time to cause thermal damage to the interior of the foramen ovale, currently a temperature of 85 degrees centigrade is reached for 30 seconds. The RF energy is then stopped. The foramen ovale catheter is then withdrawn into the single lumen catheter and then removed from the patient. All the catheters are then removed and the puncture site is sealed using standard techniques.

The trauma created within the foramen ovale starts a healing process which over time seals the foramen ovale shut with scar tissue. Once the foramen ovale is shut, the patient no longer has the risks associated with an patent foramen ovale.

While several particular embodiments of the invention have been illustrated and described, it will be apparent that various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited except as by the appended claims.

What is Claimed is:

1. A radio frequency catheter device for thermally traumatizing a patent foramen ovale comprising:
   A a sheath catheter with proximal and distal ends;
   B a foramen ovale catheter deployably retained within the sheath catheter, the foramen ovale catheter having proximal and distal ends;
   C at least one radio frequency electrode attached to the foramen ovale catheter at its distal end;
   D a supply of radio frequency energy attached to the electrode.

2. The catheter device of claim 1 wherein the electrode is attached to the outer circumference of the catheter.

3. The catheter device of claim 1 wherein the electrode is attached to the distal end of the catheter..

4. The catheter device of claim 1 wherein the electrode protrudes from the distal end of the catheter.

5. The catheter device of claim 1 wherein the electrode is shaped like a paddle.

6. The catheter device of claim 1 wherein a plurality of electrodes are attached to the distal end and at least one electrode is a negative electrode and a different electrode is a positive electrode..

7. The catheter device of claim 1 further comprising means for monitoring the temperature of tissue that comes into contact with the electrode.

8. The catheter device of claim 7 wherein the monitoring means is a thermocouple attached to the electrode.

9. A method of thermally traumatizing a patent foramen ovale comprising the steps of:

A inserting an introducer catheter into a vessel of a patient with a patent foramen ovale;

B inserting a foramen ovale catheter with proximal and distal ends and with at least one electrode attached to or near the distal end through the introducer catheter;

C advancing the foramen ovale catheter through the patent foramen ovale;

D applying radio frequency energy to the electrode to thermally traumatize the interior of the patent foramen ovale;

E removing the foramen ovale catheter and the introducer catheter from the patient.

10. The method of thermally traumatizing a patent foramen ovale of claim 9 further comprising the step of inserting a sheath catheter through the introducer catheter.

11. A method of training a person to perform the method of thermally traumatizing a patent foramen ovale comprising the steps of demonstrating or instructing the performance of the method of claim 9.

12. The method of training a person of claim 16 further comprising the step of claim 10.

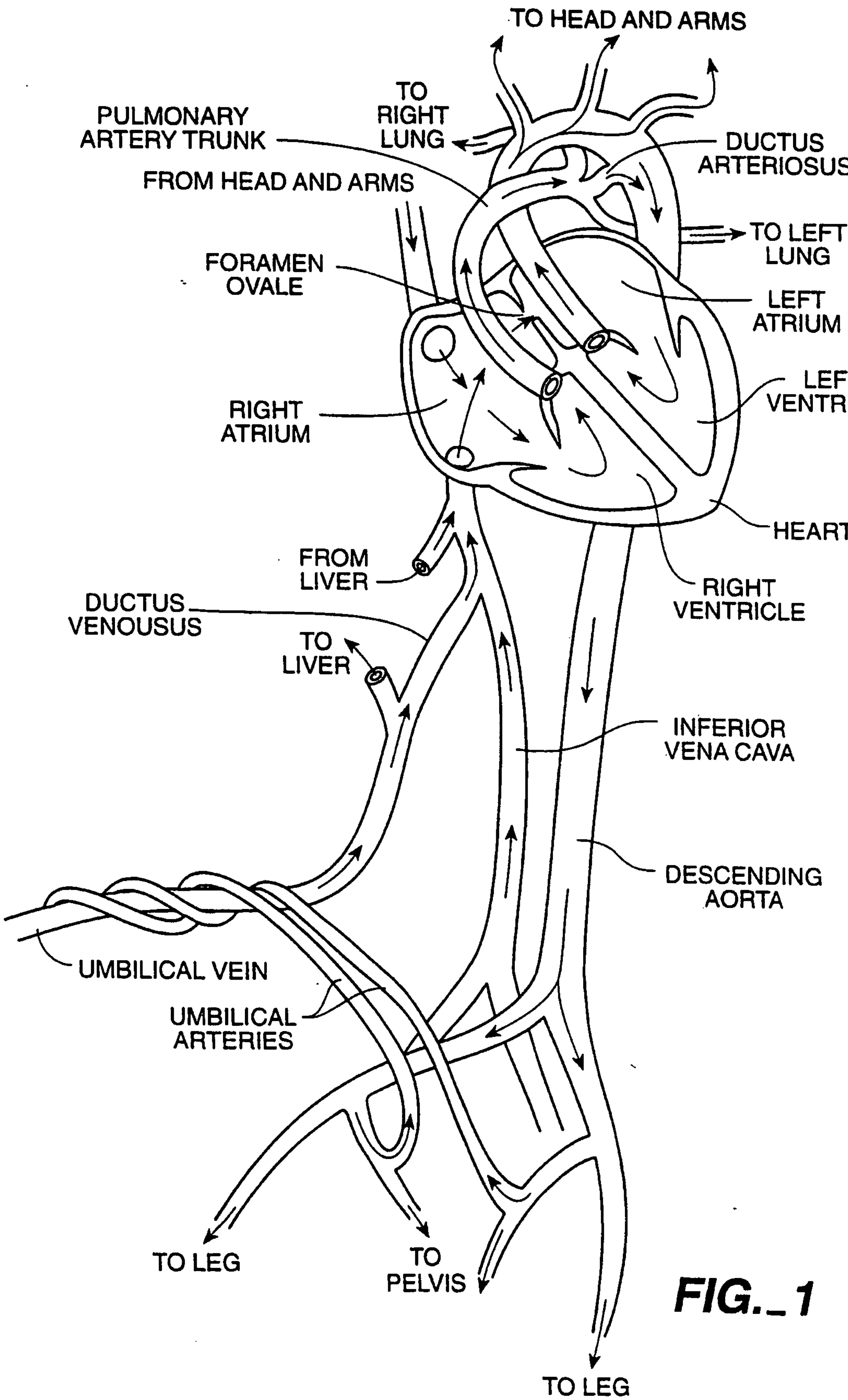
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FIG._1

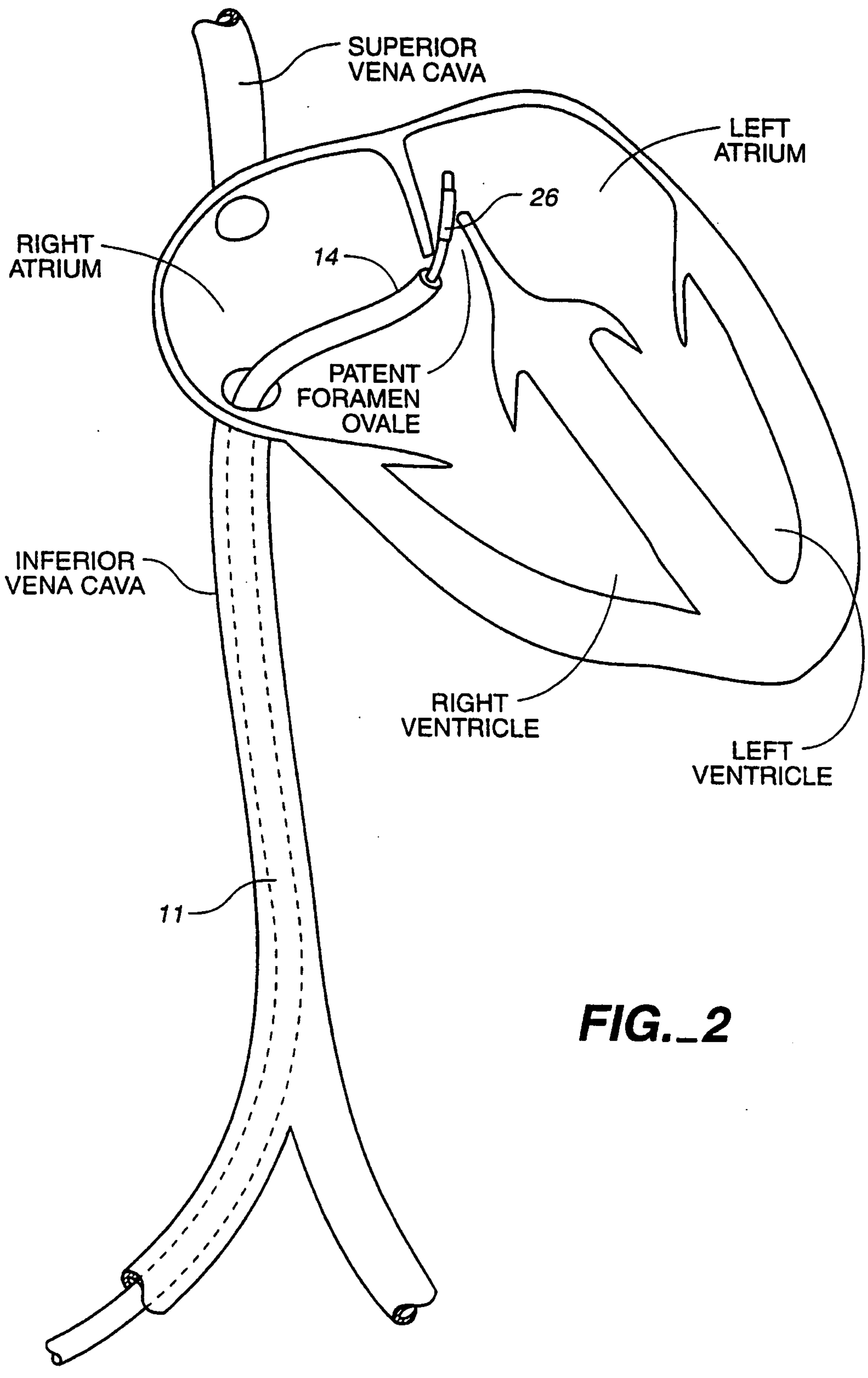
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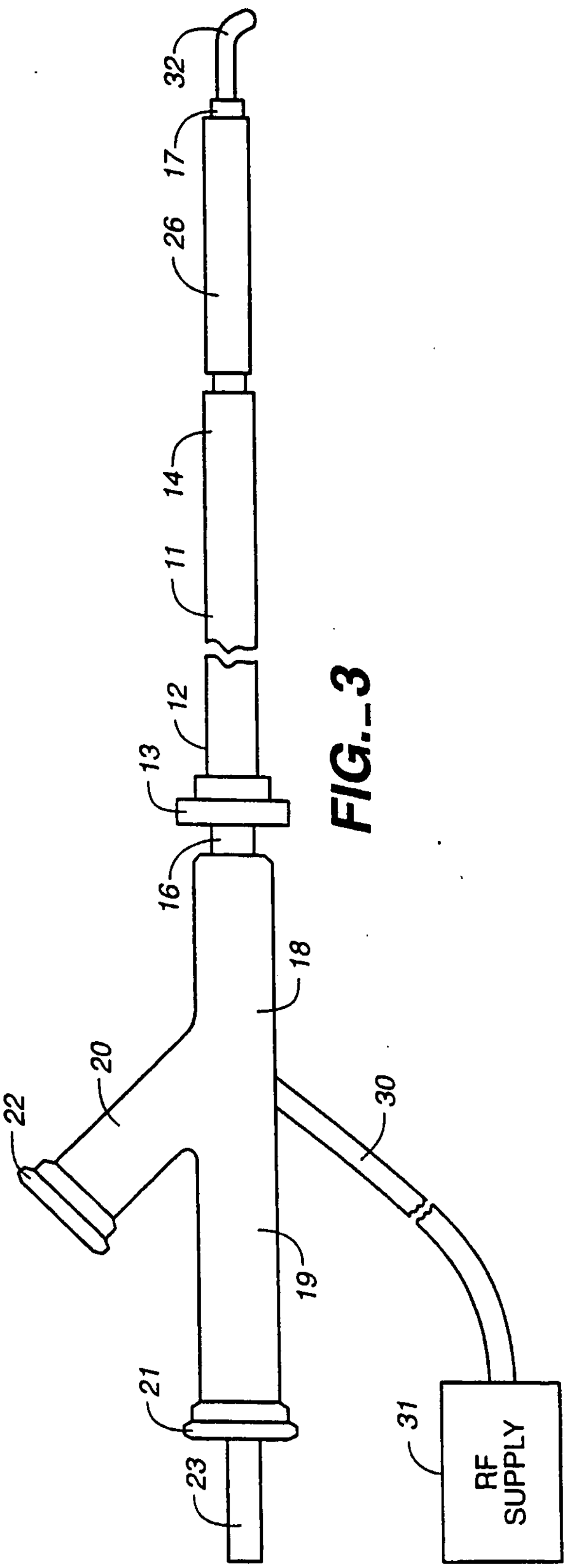
FIG._2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RF SUPPLY

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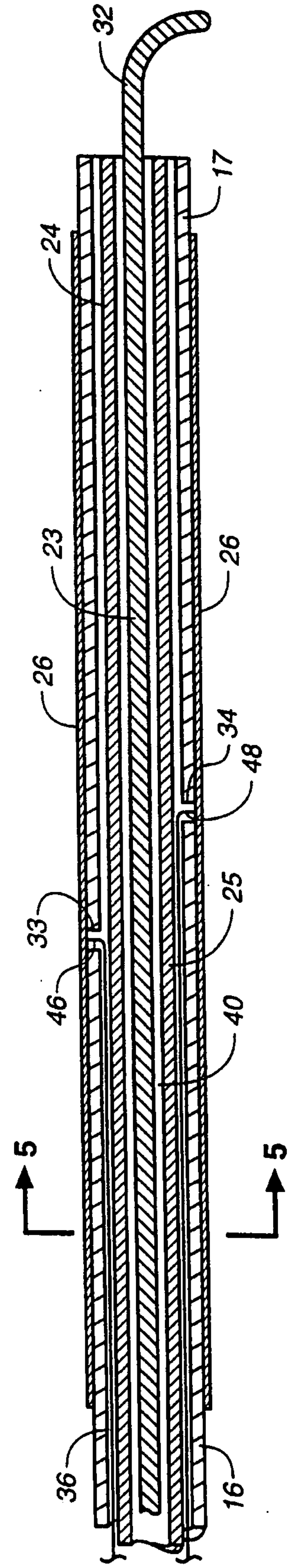
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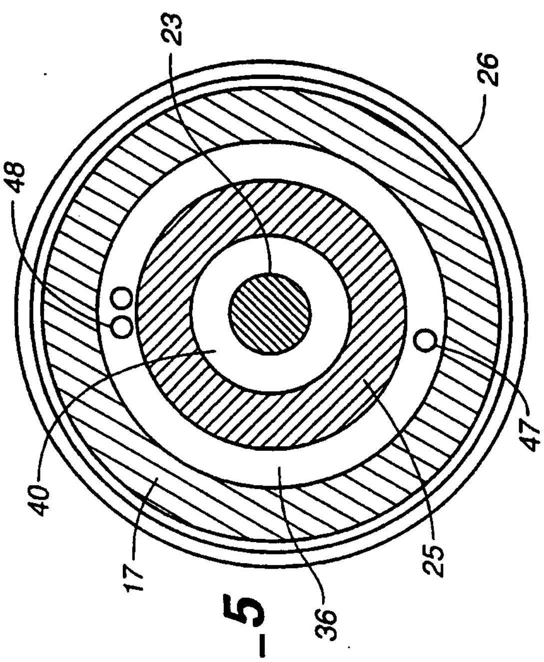
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FIG._5

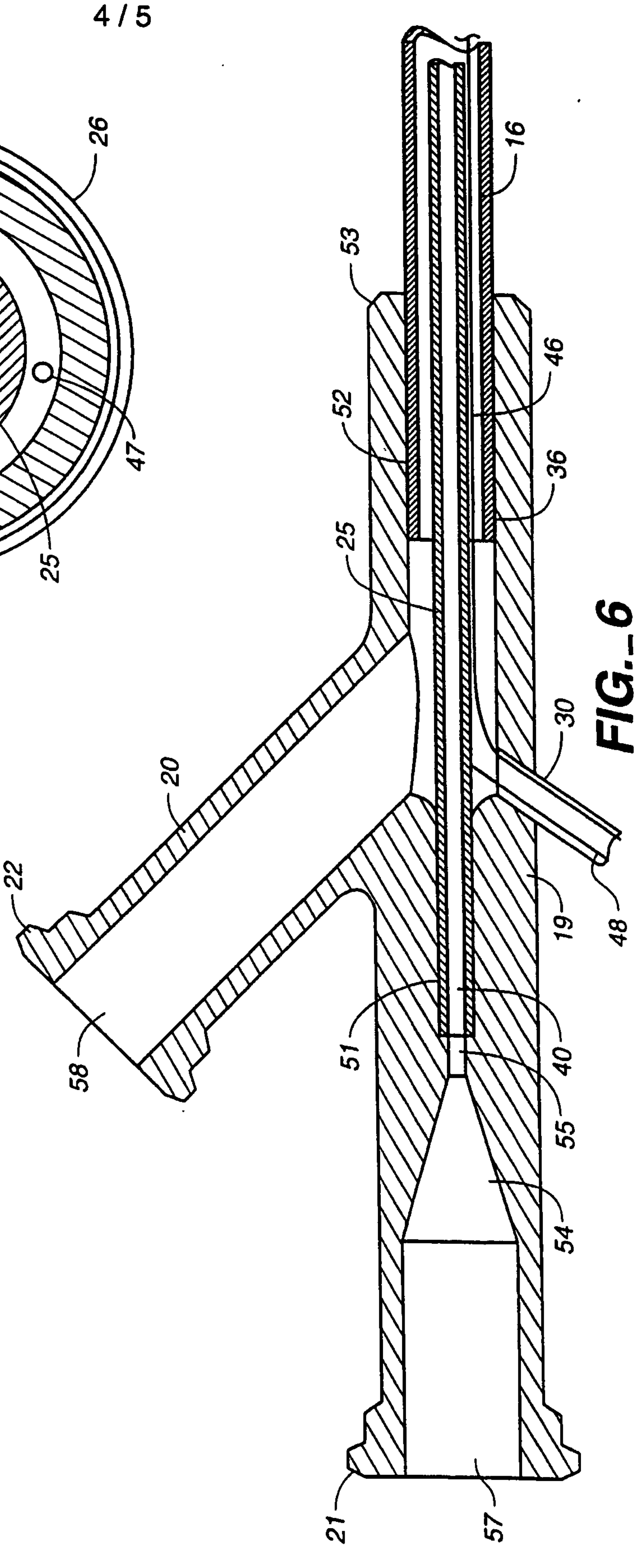
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FIG._6

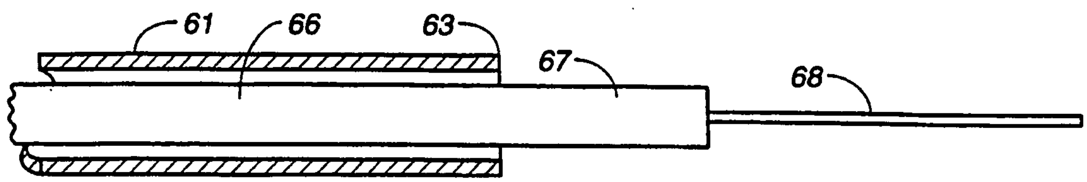

FIG._7

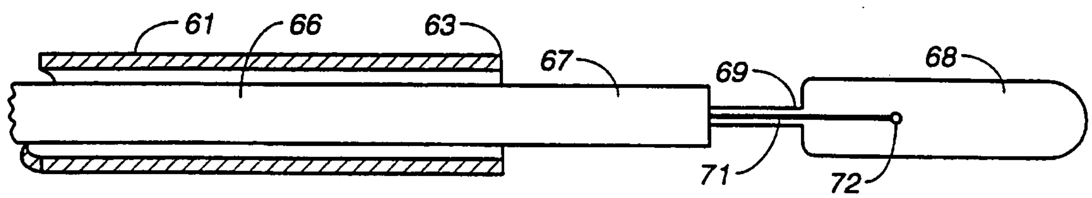

FIG._8

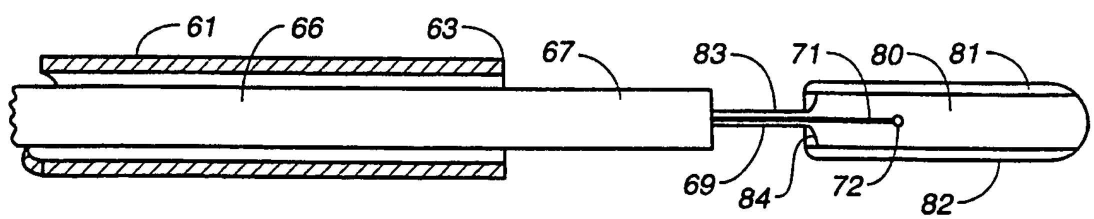

FIG._9

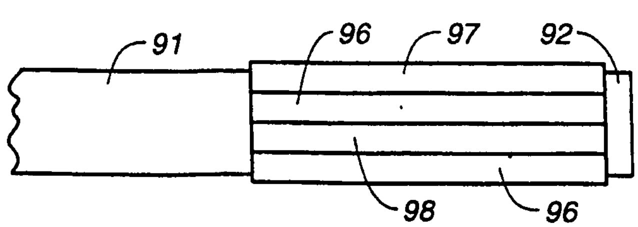

FIG._10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/21459

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/39
US CL :606/28, 41, 45, 49, 50; 607/99, 101, 122
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/28, 41, 45, 49, 50; 607/99, 101, 122

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,564,440 A (SWARTZ et al) 15 October 1996, entire document.	1-4, 6
Y	US 5,545,161 A (IMRAN) 13 August 1996, entire document.	9-12
X	US 5,460,629 A (SHLAIN et al) 24 October 1995, entire document.	1-6
Y	US 5,571,088 A (LENNOX et al) 05 November 1996, entire document.	1-4, 6-8
Y	US 5,647,871 A (LEVINE et al) 15 July 1997, entire document.	1-8
Y	US 5,545,161 A (IMRAN) 13 August 1996, entire document.	1-4, 6-8

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"P" document published prior to the international filing date but later than the priority date claimed

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 DECEMBER 1998	20 JAN 1999

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